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Attorneys for Defendants Novartis Pharmaceuticals Corporation

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

ANN MONSUE, as Administratrix of the Estate of CLYDE MONSUE, Deceased,

Plaintiff,

-against-

PFIZER INC., PARKE-DAVIS, a division of Warner-Lambert Company and Warner-Lambert Company LLC, WARNER-LAMBERT COMPANY, WARNER LAMBERT COMPANY LLC, EON LABS, INC., SANDOZ INC. and NOVARTIS PHARMACEUTICALS CORPORATION,

Civil Action No.: 08 Civ. 6993 (RJS) (DF)

ECF Case

Defendants.

ANSWER, AFFIRMATIVE DEFENSES, AND JURY DEMAND OF DEFENDANT NOVARTIS PHARMACEUTICALS CORPORATION

Defendant Novartis Pharmaceuticals Corporation (hereinafter "Novartis"), by and through its counsel, hereby answers Plaintiff's Verified Complaint ("Complaint"). Novartis denies any allegations contained in the headings or unnumbered paragraphs of the Complaint. In response to the specific allegations of the Complaint, Novartis states:

STATEMENT OF THE CASE

Novartis denies the allegations of paragraph 1 of the Complaint. 1.

PARTIES AND JURISDICTION

- Novartis is without knowledge or information sufficient to form a belief as to the 2. truth of the allegations of paragraph 2 of the Complaint and therefore denies them.
- 3. Novartis is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3 of the Complaint and therefore denies them.
- 4. Novartis is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the Complaint and therefore denies them.
- 5. The allegations in paragraph 5 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 6 of the Complaint are not directed at Novartis, and 6. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 7 of the Complaint are not directed at Novartis, and 7. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 8 of the Complaint are not directed at Novartis, and 8. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 9 of the Complaint are not directed at Novartis, and 9. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 10. The allegations in paragraph 10 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 11. The allegations in paragraph 11 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 12. The allegations in paragraph 12 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 13. The allegations in paragraph 13 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 14. The allegations in paragraph 14 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 15. The allegations in paragraph 15 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 16. The allegations in paragraph 16 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 17. The allegations in paragraph 17 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 18. The allegations in paragraph 18 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 19. The allegations in paragraph 19 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 20. The allegations in paragraph 20 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 21. The allegations in paragraph 21 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 22. The allegations in paragraph 22 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 23. The allegations in paragraph 23 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 24. The allegations in paragraph 24 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations
- 25. Novartis admits that it is a Delaware corporation with its principal place of business at 59 Route 10, East Hanover, New Jersey 07936. Novartis denies any remaining allegations contained in paragraph 25 of the Complaint.
- 26. Novartis admits that it is a Delaware corporation and, at all relevant times, has been authorized to do business in the State of New York. Novartis denies any remaining allegations contained in paragraph 26 of the Complaint.
- 27. Novartis admits that it is a Delaware corporation and, at all relevant times, has being doing business in the State of New York. Novartis denies any remaining allegations contained in paragraph 27 of the Complaint.
- 28. The allegations in paragraph 28 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 29. The allegations in paragraph 29 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 30. The allegations in paragraph 30 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 31. The allegations in paragraph 31 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 32. The allegations in paragraph 32 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 33. The allegations in paragraph 33 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 34. The allegations in paragraph 34 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 35. The allegations in paragraph 35 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 36. The allegations in paragraph 36 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 37. The allegations in paragraph 37 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 38. The allegations in paragraph 38 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 39. The allegations in paragraph 39 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 40. The allegations in paragraph 40 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 41. The allegations in paragraph 41 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 42. The allegations in paragraph 42 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 43. The allegations in paragraph 43 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 44. The allegations in paragraph 44 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 45. The allegations in paragraph 45 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 46. The allegations in paragraph 46 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 47. The allegations in paragraph 47 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 48. The allegations in paragraph 48 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 49. The allegations in paragraph 49 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 50. The allegations in paragraph 50 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 51. The allegations in paragraph 51 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 52. The allegations in paragraph 52 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 53. The allegations in paragraph 53 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 54. The allegations in paragraph 54 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 55. The allegations in paragraph 55 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 56. The allegations in paragraph 56 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 57. The allegations in paragraph 57 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 58. The allegations in paragraph 58 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- The allegations in paragraph 59 of the Complaint are not directed at Novartis, and 59. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 60 of the Complaint are not directed at Novartis, and 60. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 61 of the Complaint are not directed at Novartis, and 61. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 62 of the Complaint are not directed at Novartis, and 62. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 63 of the Complaint are not directed at Novartis, and 63. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 64 of the Complaint are not directed at Novartis, and 64. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 65 of the Complaint are not directed at Novartis, and 65. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 66. The allegations in paragraph 66 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 67. The allegations in paragraph 67 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 68. The allegations in paragraph 68 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 69. The allegations in paragraph 69 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 70. The allegations in paragraph 70 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 71. The allegations in paragraph 71 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 72. The allegations in paragraph 72 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 73. The allegations in paragraph 73 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 74. The allegations in paragraph 74 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 75. The allegations in paragraph 75 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 76. The allegations in paragraph 76 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 77. The allegations in paragraph 77 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 78. The allegations in paragraph 78 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 79. The allegations in paragraph 79 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- The allegations in paragraph 80 of the Complaint are not directed at Novartis, and 80. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
 - Novartis denies the allegations of paragraph 81 of the Complaint. 81.
 - 82. Novartis denies the allegations of paragraph 82 of the Complaint.
- The allegations in paragraph 83 of the Complaint are not directed at Novartis, and 83. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 84 of the Complaint are not directed at Novartis, and 84. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
 - 85. Novartis denies the allegations of paragraph 85 of the Complaint.
 - Novartis denies the allegations of paragraph 86 of the Complaint. 86.
 - Novartis denies the allegations of paragraph 87 of the Complaint. 87.
 - Novartis denies the allegations of paragraph 88 of the Complaint. 88.
- The allegations in paragraph 89 of the Complaint are not directed at Novartis, and 89. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 90 of the Complaint are not directed at Novartis, and 90. therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 91. The allegations in paragraph 91 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 92. The allegations in paragraph 92 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 93. The allegations in paragraph 93 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 94. The allegations in paragraph 94 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 95. The allegations in paragraph 95 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 96. The allegations in paragraph 96 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 97. The allegations in paragraph 97 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 98. The allegations in paragraph 98 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 99. The allegations in paragraph 99 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 100. The allegations in paragraph 100 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 101. The allegations in paragraph 101 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 102. The allegations in paragraph 102 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 103. The allegations in paragraph 103 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 104. The allegations in paragraph 104 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 105. The allegations in paragraph 105 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 106. The allegations in paragraph 106 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 107. The allegations in paragraph 107 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 108 of the Complaint are not directed at Novartis, 108. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 109. The allegations in paragraph 109 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 110. The allegations in paragraph 110 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 111 of the Complaint are not directed at Novartis, 111. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 112. The allegations in paragraph 112 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 113. The allegations in paragraph 113 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 114. The allegations in paragraph 114 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 115. The allegations in paragraph 115 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 116. The allegations in paragraph 116 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 117. The allegations in paragraph 117 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 118. The allegations in paragraph 118 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 119. The allegations in paragraph 119 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 120. The allegations in paragraph 120 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 121. The allegations in paragraph 121 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 122. The allegations in paragraph 122 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 123. The allegations in paragraph 123 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 124. The allegations in paragraph 124 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 125. The allegations in paragraph 125 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

denies such allegations.

- 126. The allegations in paragraph 126 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis
- 127. The allegations in paragraph 127 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 128. The allegations in paragraph 128 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 129. The allegations in paragraph 129 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 130. The allegations in paragraph 130 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
 - 131. Novartis denies the allegations of paragraph 131 of the Complaint.
 - 132. Novartis denies the allegations of paragraph 132 of the Complaint.
- 133. Novartis admits that it sells certain FDA-approved pharmaceutical products in the State of New York. Novartis denies any remaining allegations contained in paragraph 133 of the Complaint.
 - 134. Novartis denies the allegations of paragraph 134 of the Complaint.
 - 135. Novartis denies the allegations of paragraph 135 of the Complaint.

- 136. Novartis admits that it sells certain FDA-approved pharmaceutical products in the State of New York. Novartis denies any remaining allegations contained in paragraph 136 of the Complaint.
- 137. Novartis admits that it sells certain FDA-approved pharmaceutical products in interstate commerce. Novartis denies any remaining allegations contained in paragraph 137 of the Complaint.

BACKGROUND

STATEMENT OF THE CASE

- 138. The allegations in paragraph 138 of the Complaint are based upon FDA statutes and regulations that speak for themselves, and therefore no response is required. To the extent a response is necessary, Novartis denies the allegations.
- 139. In response to the allegations in paragraph 139 of the Complaint, Novartis admits that physicians may prescribe drugs for unapproved uses, which are referred to as "off-label" uses. Novartis denies any remaining allegations contained in paragraph 139 of the Complaint.
- 140. The allegations in paragraph 140 of the Complaint are based upon FDA statutes and regulations that speak for themselves, and therefore no response is required. To the extent a response is necessary, Novartis denies the allegations.
- 141. The allegations in paragraph 141 of the Complaint are based upon FDA statutes and regulations that speak for themselves, and therefore no response is required. To the extent a response is necessary, Novartis denies the allegations.
- 142. The allegations in paragraph 142 of the Complaint are based upon FDA statutes and regulations that speak for themselves, and therefore no response is required. To the extent a response is necessary, Novartis denies the allegations.

- 143. The allegations in paragraph 143 of the Complaint are based upon FDA statutes and regulations that speak for themselves, and therefore no response is required. To the extent a response is necessary, Novartis denies the allegations.
- 144. The allegations in paragraph 144 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 145. Novartis is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 145 of the Complaint and therefore denies them.
- 146. The allegations in paragraph 146 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 147. The allegations in paragraph 147 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 148. The allegations in paragraph 148 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 149. The allegations in paragraph 149 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 150. The allegations in paragraph 150 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- The allegations in paragraph 151 of the Complaint are not directed at Novartis, 151. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 152 of the Complaint are not directed at Novartis, 152. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 153 of the Complaint are not directed at Novartis, 153. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 154 of the Complaint are not directed at Novartis, 154. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 155 of the Complaint are not directed at Novartis, 155. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 156. The allegations in paragraph 156 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 157. Novartis is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 157 of the Complaint and therefore denies them.
- 158. The allegations in paragraph 158 of the Complaint are based upon FDA statutes and regulations that speak for themselves, and therefore no response is required. To the extent a response is necessary, Novartis denies the allegations.

- 159. The allegations in paragraph 159 of the Complaint are based upon FDA statutes and regulations that speak for themselves, and therefore no response is required. To the extent a response is necessary, Novartis denies the allegations.
- 160. The allegations in paragraph 160 of the Complaint are based upon FDA statutes and regulations that speak for themselves, and therefore no response is required. To the extent a response is necessary, Novartis denies the allegations.
- 161. The allegations in paragraph 161 of the Complaint are based upon FDA statutes and regulations that speak for themselves, and therefore no response is required. To the extent a response is necessary, Novartis denies the allegations.
 - 162. Novartis denies the allegations of paragraph 162 of the Complaint.
 - 163. Novartis denies the allegations of paragraph 163 of the Complaint.
 - 164. Novartis denies the allegations of paragraph 164 of the Complaint.
- 165. Novartis is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 165 of the Complaint and therefore denies them.
 - 166. Novartis denies the allegations of paragraph 166 of the Complaint.
- 167. The allegations in paragraph 167 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 168. Novartis is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 168 of the Complaint and therefore denies them.
- 169. Novartis is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 169 of the Complaint and therefore denies them.
 - 170. Novartis denies the allegations of paragraph 170 of the Complaint.

- 171. Novartis denies the allegations of paragraph 171 of the Complaint.
- 172. Novartis denies the allegations of paragraph 172 of the Complaint.
- 173. Novartis denies the allegations of paragraph 173 of the Complaint.
- 174. Novartis admits that it may owe certain duties as defined by the FDA regulations governing prescription drugs. Novartis denies any remaining allegations contained in paragraph 174 of the Complaint.
 - 175. Novartis denies the allegations of paragraph 175 of the Complaint.
 - 176. Novartis denies the allegations of paragraph 176 of the Complaint.
 - 177. Novartis denies the allegations of paragraph 177 of the Complaint.

AS AND FOR A FIRST CAUSE OF ACTION AGAINST THE PFIZER DEFENDANTS FOR NEGLIGENCE

- 178. Novartis restates its answers to paragraphs 1 through 177 of the Complaint with the same force and legal effect as if fully set out her ein.
- 179. The allegations in paragraph 179 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 180. The allegations in paragraph 180 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 181. The allegations in paragraph 181 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- The allegations in paragraph 182 of the Complaint are not directed at Novartis, 182. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 183 of the Complaint are not directed at Novartis, 183. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 184 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 185 of the Complaint are not directed at Novartis, 185. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 186 of the Complaint are not directed at Novartis, 186. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

AS AND FOR A SECOND CAUSE OF ACTION AGAINST THE PFIZER DEFENDANTS FOR BREACH OF WARRANTY

- Novartis restates its answers to paragraphs 1 through 186 of the Complaint with 187. the same force and legal effect as if fully set out herein.
- The allegations in paragraph 188 of the Complaint are not directed at Novartis, 188. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 189. The allegations in paragraph 189 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 190. The allegations in paragraph 190 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 191. The allegations in paragraph 191 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 192. The allegations in paragraph 192 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 193. The allegations in paragraph 193 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 194. The allegations in paragraph 194 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

AS AND FOR A THIRD CAUSE OF ACTION AGAINST THE PFIZER DEFENDANTS FOR PRODUCTS LIABILITY

195. Novartis restates its answers to paragraphs 1 through 194 of the Complaint with the same force and legal effect as if fully set out herein.

- 196. The allegations in paragraph 196 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 197. The allegations in paragraph 197 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 198. The allegations in paragraph 198 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 199. The allegations in paragraph 199 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

AS AND FOR A FOURTH CAUSE OF ACTION AGAINST THE PFIZER DEFENDANTS FOR FRAUDULENT MISREPRESENTATION

- 200. Novartis restates its answers to paragraphs 1 through 199 of the Complaint with the same force and legal effect as if fully set out herein.
- 201. The allegations in paragraph 201 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 202. The allegations in paragraph 202 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 203. The allegations in paragraph 203 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 204 of the Complaint are not directed at Novartis, 204. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 205 of the Complaint are not directed at Novartis, 205. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 206 of the Complaint are not directed at Novartis, 206. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 207. The allegations in paragraph 207 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 208 of the Complaint are not directed at Novartis, 208. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 209 of the Complaint are not directed at Novartis, 209. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 210. The allegations in paragraph 210 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 211. The allegations in paragraph 211 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 212. The allegations in paragraph 212 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 213. The allegations in paragraph 213 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 214. The allegations in paragraph 214 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 215. The allegations in paragraph 215 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 216. The allegations in paragraph 216 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 217. The allegations in paragraph 217 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 218. The allegations in paragraph 218 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 219. The allegations in paragraph 219 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 220. The allegations in paragraph 220 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 221. The allegations in paragraph 221 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 222. The allegations in paragraph 222 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 223. The allegations in paragraph 223 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 224. The allegations in paragraph 224 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 225. The allegations in paragraph 225 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 226. The allegations in paragraph 226 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 227. The allegations in paragraph 227 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 228. The allegations in paragraph 228 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 229. The allegations in paragraph 229 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 230. The allegations in paragraph 230 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 231. The allegations in paragraph 231 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 232. The allegations in paragraph 232 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 233. The allegations in paragraph 233 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 234. The allegations in paragraph 234 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 235. The allegations in paragraph 235 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 236. The allegations in paragraph 236 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 237. The allegations in paragraph 237 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 238. The allegations in paragraph 238 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 239 of the Complaint are not directed at Novartis, 239. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 240 of the Complaint are not directed at Novartis, 240. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 241. The allegations in paragraph 241 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 242. The allegations in paragraph 242 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 243. The allegations in paragraph 243 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 244. The allegations in paragraph 244 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 245. The allegations in paragraph 245 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 246. The allegations in paragraph 246 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 247. The allegations in paragraph 247 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 248. The allegations in paragraph 248 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 249. The allegations in paragraph 249 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 250. The allegations in paragraph 250 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 251. The allegations in paragraph 251 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- 252. The allegations in paragraph 252 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 253 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 254. The allegations in paragraph 254 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 255 of the Complaint are not directed at Novartis. 255. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 256. The allegations in paragraph 256 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 257. The allegations in paragraph 257 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 258. The allegations in paragraph 258 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

- The allegations in paragraph 259 of the Complaint are not directed at Novartis, 259. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 260. The allegations in paragraph 260 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 261. The allegations in paragraph 261 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- The allegations in paragraph 263 of the Complaint are not directed at Novartis, 262. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 263. The allegations in paragraph 263 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 264. The allegations in paragraph 264 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 265. The allegations in paragraph 265 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

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- 266. The allegations in paragraph 266 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 267. The allegations in paragraph 267 of the Complaint are not directed at Novartis. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 268. The allegations in paragraph 268 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 269. The allegations in paragraph 269 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

AS AND FOR A FIFTH CAUSE OF ACTION AGAINST THE PFIZER DEFENDANTS FOR **VIOLATION OF TENNESSEE CONSUMER PROTECTION STATUTES**

- 270. Novartis restates its answers to paragraphs 1 through 269 of the Complaint with the same force and legal effect as if fully set out herein.
- 271. The allegations in paragraph 271 of the Complaint are not directed at Novartis. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.
- 272. The allegations in paragraph 272 of the Complaint are not directed at Novartis. and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

273. The allegations in paragraph 273 of the Complaint are not directed at Novartis, and therefore no response is necessary. To the extent a response is deemed necessary, Novartis denies such allegations.

AS AND FOR A SIXTH CAUSE OF ACTION AGAINST THE EON DEFENDANTS FOR NEGLIGENCE

- 274. Novartis restates its answers to paragraphs 1 through 273 of the Complaint with the same force and legal effect as if fully set out herein.
 - 275. Novartis denies the allegations of paragraph 275 of the Complaint.
 - 276. Novartis denies the allegations of paragraph 276 of the Complaint.
 - 277. Novartis denies the allegations of paragraph 277 of the Complaint.
 - 278. Novartis denies the allegations of paragraph 278 of the Complaint.
 - 279. Novartis denies the allegations of paragraph 279 of the Complaint.
 - 280. Novartis denies the allegations of paragraph 280 of the Complaint.
 - 281. Novartis denies the allegations of paragraph 281 of the Complaint.

AS AND FOR A SEVENTH CAUSE OF ACTION AGAINST THE EON DEFENDANTS FOR BREACH OF WARRANTY

- Novartis restates its answers to paragraphs 1 through 281 of the Complaint with 282. the same force and legal effect as if fully set out herein.
 - 283. Novartis denies the allegations of paragraph 283 of the Complaint.
 - Novartis denies the allegations of paragraph 284 of the Complaint. 284.
 - 285. Novartis denies the allegations of paragraph 285 of the Complaint.
 - 286. Novartis denies the allegations of paragraph 286 of the Complaint.
 - Novartis denies the allegations of paragraph 287 of the Complaint. 287.
 - 288. Novartis denies the allegations of paragraph 288 of the Complaint.
 - 289. Novartis denies the allegations of paragraph 289 of the Complaint.

AS AND FOR AN EIGHTH CAUSE OF ACTION AGAINST THE EON DEFENDANTS FOR PRODUCTS LIABILITY

- 290. Novartis restates its answers to paragraphs 1 through 289 of the Complaint with the same force and legal effect as if fully set out herein.
 - 291. Novartis denies the allegations of paragraph 291 of the Complaint.
 - 292. Novartis denies the allegations of paragraph 292 of the Complaint.
 - 293. Novartis denies the allegations of paragraph 293 of the Complaint.
 - 294. Novartis denies the allegations of paragraph 294 of the Complaint.

AS AND FOR A NINTH CAUSE OF ACTION AGAINST ALL DEFENDANTS

- 295. Novartis restates its answers to paragraphs 1 through 294 of the Complaint with the same force and legal effect as if fully set out herein.
- 296. Novartis is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 296 of the Complaint and therefore denies them.
- 297. Novartis is without knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 297 of the Complaint and therefore denies them.
- 298. Novartis denies the allegations of paragraph 298 of the Complaint, including all subparts, and denies that Plaintiff is entitled to the requested relief.

GENERAL DENIAL

Novartis denies all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not previously been specifically admitted, denied, or explained.

<u>AFFIRMATIVE AND OTHER DEFENSES</u>

Discovery and investigation may reveal that one or more of the following defenses should be available to Novartis. As such, Novartis asserts these defenses to preserve its right to do so. If upon the completion of discovery the facts do not support a particular defense, Novartis

will withdraw that and any other defense as may be appropriate. Further, Novartis reserves the right to amend this Answer to assert additional defenses as discovery proceeds. With respect to its defenses, Novartis states:

- 1. Plaintiff's Complaint and each count thereof fails to state a claim upon which relief may be granted.
- Plaintiff has no standing to bring this action and/or to seek the relief requested in the Complaint.
- 3. Plaintiff's claims should be dismissed and/or transferred due to improper and/or inconvenient venue.
- 4. Plaintiff failed to join all necessary and appropriate parties.
- 5. Plaintiff's claims should be severed due to misjoinder.
- 6. Any Novartis product, if in fact taken by Plaintiff's decedent, did not cause or contribute to his injuries.
- 7. Plaintiff and/or Plaintiff's decedent did not suffer any physical injuries that were proximately caused by any act or omission by Novartis.
- 8. Plaintiff's claims under New York law or any other applicable state law are barred by the doctrine of federal preemption.
- 9. The causes of action asserted by Plaintiff, if she is unable to identify Novartis as the manufacturer of the alleged injury-producing product, fail to state a claim upon which relief can be granted in that Plaintiff has asserted claims for relief which, if granted, would contravene the constitutional right of Novartis to equal protection of the laws and right to substantive and procedural due process of the law as preserved for Novartis by

- the Fourteenth Amendment to the United States Constitution and by comparable guarantees in any state constitutions, including the State of New York.
- 10. The causes of action asserted by Plaintiff, if she is unable to identify Novartis as the manufacturer of the alleged injury-producing product, fail to state a claim upon which relief can be granted in that the Plaintiff has asserted claims for relief which, if granted, would constitute a taking of private property, for public use, without just compensation. Such a taking would contravene the constitutional rights of Novartis as preserved for Novartis by the Fourteenth Amendment to the United States Constitution and by comparable guarantees in any state constitutions, including the State of New York.
- 11. The causes of action asserted by Plaintiff, if she is unable to identify Novartis as the manufacturer of the alleged injury-producing product, fail to state a claim upon which relief can be granted in that Plaintiff has asserted claims for relief which, if granted, would constitute a denial of Novartis's constitutional rights under the Commerce Clause of Article I, § 8 of the United States Constitution.
- 12. Plaintiff's claims are barred in whole or in part by the applicable statutes of limitation, repose, and the doctrine of laches.
- 13. Plaintiff's claims are barred, in whole or in part, because Novartis did not owe a duty to Plaintiff or breach any duty to Plaintiff and/or Plaintiff's decedent.
- 14. At all relevant times, Novartis acted reasonably, appropriately, and lawfully pursuant to its obligations under statute and common law.
- 15. Some or all of Plaintiff's claims are barred in whole or in part because Novartis did not sell, design, or manufacture the product that allegedly caused Plaintiff's injuries, and, therefore, is not liable to Plaintiff.

- 16. Any Novartis product was not unreasonably dangerous in construction or composition at the time it left Novartis's control as it did not deviate in any way from the mandatory specifications of Novartis and the FDA.
- 17. Plaintiff's claims are barred, in whole or in part, because Novartis complied with all applicable state and federal statutes and with the requirements and regulations of the FDA.
- 18. If Plaintiff consumed any Novartis product, such product was not unreasonably dangerous due to inadequate warning; Novartis provided all warnings and other product information as required by FDA rules and regulations. The physician who prescribed the drug for Plaintiff's decedent was a fully competent learned intermediary. Novartis has no control over third parties or their compliance with the rules, regulations or standards of care.
- 19. Novartis provided adequate and complete warnings to Plaintiff's decedent's prescribing physicians for any Novartis product consumed by Plaintiff's decedent. Therefore, any claims by Plaintiff for inadequate warnings are controlled by, and barred under, the learned intermediary doctrine.
- 20. Based on the state of scientific, medical, and technological knowledge at the time, any Novartis product provided to Plaintiff's decedent was reasonably safe for normal and foreseeable use at all relevant times.
- 21. The benefits of prescription products such as those manufactured and sold by Novartis outweigh the risks, if any, and therefore such products are not defective or unreasonably dangerous.

- 22. Plaintiff's causes of action are barred in whole or in part by Plaintiff's and/or Plaintiff's decedent's comparative and/or contributory negligence.
- 23. Plaintiff's damages, if any and if they were caused by any Novartis product, were caused in whole or in part by misuse or unintended use of the product.
- 24. Plaintiff and/or Plaintiff's decedent was a knowledgeable user and, therefore, Novartis is not legally responsible for either the acts or omissions of the knowledgeable user or misinformation or lack of information provided to them by others.
- 25. Plaintiff's claims against Novartis are barred under the principles of assumption of the risk and/or informed consent.
- 26. Plaintiff and/or Plaintiff's decedent failed to exercise ordinary care under the circumstances and such failure was the substantial cause of the occurrence that caused injury or damage, if any, to Plaintiff.
- 27. Plaintiff is not entitled to recovery as a result of Plaintiff's decedent's failure to heed warnings and instructions provided by Novartis.
- 28. Plaintiff's injuries, if any, were caused by pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases, or illnesses of Plaintiff's decedent.
- 29. Plaintiff is barred from recovering any damages because the dangers, if any, claimed by Plaintiff, were "open and obvious."
- 30. Some or all of Plaintiff's claims are barred by the doctrine of spoliation.
- 31. Any alleged injuries and damages were caused, in whole or in part, by the independent conduct of one or more persons or entities over whom Novartis had no control and for whose actions or omissions Novartis may not be held accountable.

- 32. Plaintiff's damages, if any and if they were caused by any Novartis product, were caused by changes and/or alterations to the product made by persons not within Novartis's control.
- 33. Any injuries sustained by the Plaintiff and/or Plaintiff's decedent were proximately caused by the intervening and superseding acts and/or omissions of other persons or entities, and Novartis is not accountable for the acts of these other persons or entities.
- 34. Plaintiff's damages resulted from new and independent, unforeseeable, superseding and/or intervening causes unrelated to any conduct of, or product placed in the stream of commerce by, Novartis.
- 35. Plaintiff's alleged damages were the result of pre-existing or subsequent conditions unrelated to any conduct of or product placed in the stream of commerce by Novartis.
- 36. Plaintiff's alleged damages were the result of an idiosyncratic reaction, which could not have been reasonably foreseen.
- 37. The damages recoverable by Plaintiff, if any, must be reduced by any amount of damages legally caused by Plaintiff's failure to mitigate such damages in whole or in part.
- 38. Each item of economic loss alleged in Plaintiff's Complaint was, or with reasonable certainty, will be, replaced or indemnified, in whole or in part, from collateral sources.
- 39. Should Novartis be held liable to Plaintiff, and any liability is specifically denied,

 Novartis would be entitled to a set-off for all sums of money received or available from

 or on behalf of any other persons liable for the same injuries alleged in Plaintiff's

 Complaint.
- 40. Plaintiff has failed to state a claim upon which attorneys' fees and/or costs can be awarded.

- 41. Novartis's liability for damages, if any, shall be several and not joint; Novartis requests a judicial allocation of such damages in direct proportion to Novartis's percentage of fault, if any.
- 42. To the extent that Plaintiff seeks punitive damages, such damages are barred because Novartis's conduct was not fraudulent, malicious, willful, or wanton.
- 43. To the extent Plaintiff and/or Plaintiff's decedent did not ingest a product manufactured or sold by Novartis, Plaintiff's Complaint fails to state a claim upon which relief can be granted against it.
- 44. Any Novartis product is neither defective nor unreasonably dangerous and is subject to the Comment (j) exception to section 402A to strict tort liability as defined in the Restatement (Second) of Torts.
- 45. Plaintiff's claims against Novartis are barred by Comment (k) to Section 402A of the Restatement (Second) of Torts.
- 46. Plaintiff's claims against Novartis are barred by §§ 4 and 6 of the Restatement (Third) of Torts: Products Liability.
- 47. Novartis neither made nor breached any express or implied warranties to Plaintiff.
- 48. Any Novartis product was not unreasonably dangerous for failure to conform to an express warranty.
- 49. Any Novartis product was not unreasonably dangerous for failure to conform to an implied warranty.
- 50. Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on Novartis's warranty, if any.

- 51. Plaintiff's claims of breach of express warranty and breach of implied warranty are barred because there was no privity between Novartis and Plaintiff.
- 52. Plaintiff's claims of breach of express warranty are barred because any alleged warranty was not the basis of the bargain.
- 53. Plaintiff's claims of breach of express warranty are barred because Plaintiff has failed to allege any statements made by Novartis.
- Any affirmative defenses pleaded by the other defendants and not pleaded by Novartis are incorporated herein to the extent they do not conflict with Novartis's affirmative defenses.
- Novartis hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during discovery proceedings. Novartis reserves the right to amend its answer and to further assert affirmative and other defenses.

WHEREFORE, Novartis prays for relief and judgment against plaintiff as follows:

- (a) That plaintiffs take nothing by reason of this action;
- (b) That Novartis recover its fees, costs and attorneys' fees incurred herein; and
- (c) For such further and other relief as the Court deems proper.

JURY DEMAND

Novartis demands trial by jury on all issues in this action.

Dated: August 12, 2008

Respectfully Submitted,

McKENNA LONG & ALDRIDGE LLP

By: _____

Charles E. Dorkey III (CD-8422) Timothy J. Plunkett (TP-6060) 230 Park Avenue Suite 1700 New York, NY 10169 (212) 905-8330 (212) 922-1819 (facsimile)

-and-

Ray M. Aragon, Esq. Lisa M. Norrett, Esq. 1900 K Street NW Washington, DC 20006 (202) 496-7500 (202) 496-7756 (facsimile)

Attorneys for Defendant Novartis Pharmaceuticals Corporation